# Patients' perception of postoperative pain management: validation of the International Pain Outcomes (IPO) questionnaire

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Abstract: UNLABELLED: PAIN OUT is a European Commission-funded project aiming at improving postoperative pain management. It combines a registry that can be useful for quality improvement and research using treatment and patient-reported outcome measures. The core of the project is a patient questionnaire-the International Pain Outcomes questionnaire-that comprises key patient-level outcomes of postoperative pain management, including pain intensity, physical and emotional functional interference, side effects, and perceptions of care. Its psychometric quality after translation and adaptation to European patients is the subject of this validation study. The questionnaire was administered to 9,727 patients in 10 languages in 8 European countries and Israel. Construct validity was assessed using factor analysis. Discriminant validity assessment used Mann-Whitney U tests to detect mean group differences between 2 surgical disciplines. Internal consistency reliability was calculated as Cronbach's alpha. Factor analysis resulted in a 3-factor structure explaining 53.6% of variance. Cronbach's alpha at overall scale level was high (.86), and for the 3 subscales was low, moderate, or high (range, .53-.89). Significant mean group differences between general and orthopedic surgery patients confirmed discriminant validity. The psychometric quality of the International Pain Outcomes questionnaire can be regarded as satisfactory. PERSPECTIVE: The International Pain Outcomes questionnaire provides an instrument for postoperative pain assessment and improvement of quality of care, which demonstrated good psychometric quality when translated into a variety of languages in a large European and Israeli patient population. This measure provides the basis for the first comprehensive postoperative pain registry in Europe and other countries.

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# Patients' perception of post-operative pain management: Validation of the International Pain Outcomes questionnaire (IPO)

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**Short running title:** Validation of the International Pain Outcomes questionnaire (IPO)

**Index words:** pain measurement, postoperative pain, pain registry, quality improvement, PAIN OUT, IPO

**Abstract**

PAIN OUT is a European Commission-funded project aiming at improving postoperative pain (POP) management. It combines a registry that can be useful for quality improvement (QI) and research using treatment and patient-reported outcome measures. Core of the project is a patient questionnaire - the International Pain Outcomes questionnaire (IPO) that comprises key patient level outcomes of POP management including pain intensity, physical and emotional functional interference, side effects, and perceptions of care. Its psychometric quality after translation and adaptation to European patients is the subject of this validation study. The questionnaire was administered to 9,727 patients in 10 languages in eight European countries and Israel. Construct validity was assessed using factor analysis (FA). Discriminant validity assessment used U-tests to detect mean group differences between two surgical disciplines. Internal consistency reliability was calculated as Cronbach's alpha. FA resulted in a three factor structure explaining 53.6% of variance. Cronbach's alpha at overall scale level was high (0.86), and for the 3 subscales was low, moderate, or high (range 0.53 to 0.89). Significant mean group differences between general and orthopaedic surgery patients confirmed discriminant validity. The psychometric quality of the IPO can be regarded as satisfactory.

**Perspective:** The IPO questionnaire provides an instrument for POP assessment and improvement of quality of care, which demonstrated good psychometric quality when translated to a variety of languages in a large European and Israeli patient population. This measure provides the basis for the first comprehensive POP registry in Europe and other countries.

**Key words:** pain measurement, postoperative pain, pain registry, quality improvement, PAIN OUT

## Introduction

The quality of postoperative pain management is an issue of ongoing debate[1,20,4,11]. The Global Year against Acute Pain initiated by the International Association for the Study of Pain (IASP) in 2010 demonstrated the demand for action in this area. Registries are proven tools to improve knowledge and quality of clinical care in many fields of medicine[24,31,14]. According to Glicklich & Dryer, “a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure and that serves a predetermined scientific, clinical, or policy purpose(s)”[14].Registries are able to provide a picture of medical treatment strategies applied and related patient outcomes closer to clinical routine than randomized controlled trials (RCTs) do, since they include heterogeneous patients, often elderly and those burdened with co-morbidities. Registries offer the possibility for continuous benchmarking of treatment outcomes, evaluation of interventions, and can facilitate best practice[25]. Although several registry initiatives in the field of pain exist on national level[25,27], so far, there is no comprehensive, multi-national registry in pain medicine. The European Commission funded PAIN OUT project combines a quality improvement (QI) approach with a registry and development of a clinical decision support system to advance the quality of acute postoperative pain management and research in this field in Europe[37]. Feasibility of this approach has been pilot tested and is reported elsewhere[41]. Based on the registry data, two tools are provided to clinicians to facilitate pain management in participating hospitals: a patient outcomes survey benchmark module providing online feedback for internal and external benchmarking; and a clinical decision support system based on case based reasoning. A third tool is an electronic knowledge library, providing easy access to existing guidelines in acute pain.

PAIN OUT is being developed and tested by a total of 17 research and clinical partners receiving EU funding, out of which 11 clinical sites in 9 countries (France; Germany; Italy; Israel; Romania; Spain; Sweden; Switzerland; United Kingdom) carry out data collection. International recognition in an early stage of the project led to an expansion of PAIN OUT to

the US and to a number of clinical sites worldwide (a complete list of PAIN OUT partners is provided online as **Supplemental Information 1**). Patient-reported outcomes of pain management are complemented with detailed audits of medical records that collect demographics and perioperative pain treatment information (process questionnaire). Both elements combine to form the registry. This paper reports on the European and Israeli patient outcomes data from cross-cultural translated patient surveys in the PAIN OUT Registry.

In 2010, the 17 EU funded PAIN OUT members undertook a Delphi process to determine the items to include in the patient outcome questionnaire. The Delphi process resulted in a list of items closely resembling those in the recently revised American Pain Society Patient Outcomes questionnaire (APS-POQ-R)[17]. Consequently, the group decided to use the APS-POQ-R that has established preliminary psychometrics as a starting point for the project's patient outcomes questionnaire. Several additional questions were added, as a basis for further testing of categorical scaling and adaptation of patient reported outcomes to the postoperative setting in a European population. The APS-POQ has an almost 20-year history of iterative improvement and can be regarded as an instrument with satisfactory psychometric properties[33,15,16,10]. The latest version of the APS questionnaire (the APS-POQ-R) was revised and validated in 2010[17] and covers five aspects of outcome measurement in acute pain: pain severity, interference with function, affective experience, side effects, and perceptions of care. It was adapted to the postoperative setting and translated into all languages required by the PAIN OUT project following a strict forward and backward procedure. An interdisciplinary group of experts (nurses, physicians, a psychologist, a statistician, and a computer scientist) carried out the present validation study. Therefore the purpose of this paper is to report on the psychometric quality of the questionnaire after its translation and adaptation to the requirements of the postoperative setting.

## Material and Methods

### Overview

In summary, the validation procedure was carried out in two phases (see **figure 1**). In phase one, the 23 question APS-POQ-R was supplemented with five additional items proposed by experts in the PAIN OUT group as possible alternative wording and categorical scaling (see below for details). A total of 5,134 patients from 1 to 3 sites in each of the 9 countries completed the resulting first version of the instrument between February and December 2010 that from now on is termed the International Pain Outcomes questionnaire (IPO). Results from this first phase of data collection are presented in **Supplemental Information 2**. Preliminary psychometric analysis and feedback received from patients and research assistants, resulted in further adaptation of the questionnaire. In phase two, from February until October 2011, the modified questionnaire was administered to a new group of 4,590 patients, and its psychometric properties were again assessed. Presentation of results focuses on this second assessment. Details of the two phases are described below.

**(Insert figure 1 here)**

**Material**

*Patient selection & eligibility:* The study protocol was reviewed by the Institutional Review Board or Ethics Committee at all sites. All study procedures were in accordance and compliance with the regulations and the institutions' policies and guidelines for protection of human subjects. Eligible patients were identified from inpatient orthopedic and general surgery census lists. Where research assistants did not have sufficient capacity to approach all eligible patients, PAIN OUT Standard Operating Procedures provided clear guidance on how to achieve a random selection. Surgical patients were approached in their hospital room on postoperative day number one, and invited to participate by a Research Assistant (RA) using a consent form as determined by local Institutional Review Boards. Patients had to be of consenting age (varying in the European countries from 16-18 years) or over; able to communicate; and not cognitively impaired. All patient outcome data were collected on postoperative day 1, when patients were back on the ward for at least 6 hours.

*Data acquisition:* Each of the 11 EU funded clinical sites contributing to data collection (see also online **Supplemental Information 1**) appointed a RA responsible for data collection. A training workshop was held to familiarize the RAs with the requirements of data collection. A detailed standard operating procedures manual or data dictionary was available in written form. It was intended that patients should complete the IPO independently using paper and pencil. Only in defined, exceptional cases (e.g. reading glasses not available; arm in a cast; patient too weak to fill it in independently) were interviews by the RAs allowed. The RAs also filled in a supplemental assessment form for the first 300 patients at their site, pointing out any difficulties and ambiguities with items that were encountered. After the end of phase 1, a feedback meeting with RAs was held to evaluate experiences with the IPO.

*Questionnaire:*

The APS-POQ-R covers the following areas: pain severity (4 items), pain interference with physical function (4 items) and affect (4 items), adverse effects (4 items), and perceptions of care (6 items) plus an item on use of non-pharmacological treatments deemed unreliable if obtained from medical records. The five supplemental items introduced by the PAIN OUT expert group in phase 1 of the data collection addressed categories of time spent in severe pain; patient's wish for more pain treatment than received; patient's wish for less pain treatment than received; sleep quality; and pre-operative chronic pain conditions. Taking into account the results of psychometric analysis of phase 1 data and feedback from patients and RAs, the expert group decided on a final set of items for phase 2, as presented in **Supplemental Information 3**. This final version of the IPO was re-administered and reassessed in a new prospective population of patients from the same clinical sites as in phase 1.

## Methods

*Translation procedure:* The translation of the questionnaire from English was carried out according to international scientific standards[40,3]. A translation agency working with native speakers for each language conducted the work. The questionnaire was translated by a

professional translator and by a clinician into each of the languages required by the project (Arabic, French, German, Italian, Hebrew, Romanian, Russian, Spanish, and Swedish). The agency combined these two versions into one and back-translated the synthesized version into English. These back-translations were evaluated, deviations from the original English questionnaire were discussed, and a beta version was built. This beta version was piloted with 50 patients per language, difficulties in understanding and ambiguities were documented and the items concerned were modified where necessary.

*Psychometric analysis:* Descriptive statistics (means and standard deviations or frequencies, as applicable) were calculated for all items. Construct validity was assessed by exploratory factor analysis using principal component analysis with promax rotation[29]. Given skewed distributions, the appropriateness of this approach was confirmed using the Kaiser-Meyer-Olkin-(KMO) and Bartlett tests. Reliability testing used Cronbach's alpha for internal consistency of the overall questionnaire and of the subscales identified in factor analysis[6,26]. In addition, discriminant validity was assessed using the contrasting groups approach. Specifically, we used Mann-Whitney U tests and Chi-squared tests to assess whether the questionnaire items would distinguish between general surgery and orthopaedic surgery patient-outcomes. T-tests were run in parallel for comparison purposes. All analyses were carried out using STATA/MP 10.1 and 11.0 (StataCorp, College Station, Texas, USA) and SPSS 18.0 (SPSS Inc., Chicago, Illinois, USA).

## Results

### Patient accountability and characteristics

In phases 1 and 2, the patient outcome questionnaire was completed by 5,134 and 4,590 patients, respectively. **Figure 2** shows the number of patients per clinical site. Results for the phase 1 validation process are shown in **Supplemental Information 2.**

**(Insert figure 2 here)**

Of the 6,795 patients screened in phase two, 32.5% of patients were excluded. The number of patients (%) excluded according to the different criteria can be found in **table 1**. The exclusion reasons do not add up to 32.5%, since the categories are not mutually exclusive. The proportion of female patients was 50.0%. The mean age was 54.4 years ± 17.1; range 15-103. The language versions used are displayed in **table 2**. Patients were admitted to general surgery departments in 42.1% and in orthopedic departments in 51.8% (see also **table 2**).

**Descriptive analysis of patient outcome questionnaire items**

Numeric rating scale (NRS) items are provided in **table 3a,** expressed as mean values and standard deviation. The observed range of scores (minimum and maximum) for all NRS items was 0 to 10. Means of NRS items were similar between the two phases of data collection. Frequencies for items with binary or categorical answer format are provided in **table 3b**. Occurrence of missing values was below 3% for most items. Two items using percentage scales (time spent in severe pain; pain relief achieved) and two covering perception of care topics (participation in pain treatment decisions; satisfaction) had slightly higher proportions of missing values ranging from 2.7-9.2%.

Regarding preoperative chronic pain, 49.3% of patients suffered from persistent pain before surgery, its intensity being 6.4 NRS points. In 59.9% of cases the persistent pain was at the site of surgery, in 10.8% was elsewhere, and in 29.3% was present both at the site of surgery and in other body areas. A total of 16.9% of patients would have wished more pain treatment than they received.

**Adaptation of questionnaire**

The phase 1 questionnaire showed favorable psychometric properties overall (see **Supplemental Information 2**), which supports previous work by the APS[17]. Further adaptation leading to phase 2 aimed both at shortening the instrument without loss of

substantial information and at adapting it to the needs of the European patient population. The following changes were made:

1. The two pain interference items on ‘falling asleep’ and ‘staying asleep’ were combined into a single new item asking whether ‘pain interfered with or prevented you from sleeping’, since the two original items had a high inter-item-correlation of r=.84, the highest of the whole correlation matrix.
2. A new item asking whether ‘pain interfered with or prevented you from breathing deeply or coughing’ was introduced, as this was regarded by the expert group as being of high clinical importance, especially for patients undergoing general surgery.
3. A filter question was introduced before the item on ‘interference with activities out of bed’ to separate out those patients who had not yet been out of bed at the time of being surveyed. Without such a filter, a high rate of missing answers (17.5%) was noted with the first version of the questionnaire.
4. Two of the four emotional impairment items (‘frightened’ and ‘depressed’) were removed. Both had a high inter-item correlation (r=.67 and r.=65, respectively) with the ‘anxious’ item. Apart from high inter-item correlations there were lingual and cultural reasons for taking out the two items ‘depressed’ and ‘frightened’. In many languages both translators and patients had difficulties in telling the difference between ‘frightened’ and ‘anxious’. Since ‘anxious’ was clearer to most patients we decided to keep ‘anxious’. Another reason was that many patients in various countries reacted irritated on the item ‘depressed’.
5. The item ‘How often did a nurse or doctor encourage you to use non-medicine methods?’ was removed, since in 76.5% of cases the answer was ‘never’. In addition, in some countries this item was regarded as difficult to understand.
6. Of the five items added to APS-POQ-R questionnaire, two were kept. 'Would you have liked more pain treatment than you received? (yes/no)' increased Cronbach’s alpha of the sub-scale ‘perceptions of care’ from 0.55 to 0.61. The item and sub-items addressing chronic pain were kept because of their clinical relevance and because

medical record-based information on the presence of chronic pain (as collected on the phase 1 process questionnaire) proved to not be sufficiently reliable. Of the items not included in the phase 2 questionnaire, 'would you have liked less pain treatment than you received?' (yes/no) was only answered 'yes' by 3.8 % of patients. 'Did you wake up due to pain?' slightly decreased Cronbach's alpha for the 'pain intensity and interference' sub-scale when replacing 'interference with staying asleep'. Finally, the original APS-POQ-R item 'percentage of time spent in severe pain' was not replaced by the alternative using a categorical answer format due to marginal impact on internal consistency results.

**Results after adaptation of questionnaire**

***Exploratory factor analysis***

The appropriateness of using exploratory factor analysis on the phase 2 set of 16 NRS items to assess construct validity was confirmed by the results of the KMO test (0.901) and the Bartlett test ($p < 0.001$). Principal component analysis with promax rotation was used. Pairwise exclusion of missing values resulted in case numbers ranging from 3,186 to 4,585. The factor analysis generated a three factor solution (Eigen value >1), explaining a total variance of 53.8 %. The factor loadings per item are displayed in **table 4**. The group of pain intensity and interference items forms one factor together with the two remaining 'affective impairment' items, explaining 36.0 % of variance. The factors 'adverse effects' and 'perceptions of care', explaining 10.3% and 7.5% of variance, remained unchanged.

***Internal consistency reliability***

Cronbach's alpha and related statistics is displayed in **table 5**. Overall Cronbach's alpha was 0.86. As in phase 1, the subscale 'pain intensity and interference (physical and emotional)' achieved the best Cronbach's alpha (r=.89), followed by 'adverse effects' (r=.67) and 'perceptions of care' (r=.55).

***Discriminant validity***

For all NRS items but one, a significant difference between the general surgery and orthopedic patient groups was observed (see **table 6**). Exception was 'nausea' with an almost equal mean in orthopedic and general surgery patients (1.67 and 1.75 respectively). All pain intensity items, both items on affective impairment and three interference items were significantly increased in orthopedic patients. The new item on 'pain interference with breathing/coughing' had an increased mean value in general surgery patients. Both adverse effects 'dizziness' and 'drowsiness' were also increased in general surgery patients, 'itching' was slightly increased in orthopedic patients. As in phase 1, 'percentage of pain relief' and 'satisfaction with pain treatment' showed significantly higher scores in the patients treated in general surgery, while the item 'participation in decision making' was again increased in orthopedic patients.

**Discussion**

The PAIN OUT project establishes a registry that can be used for local QI benchmarking or larger scale research studies using patient-reported outcome data, demographics, with real-world perioperative treatment details[41]. Unlike most registries that contain only medical record audit data, PAIN OUT incorporates a self-reported patient questionnaire (IPO), comprising key outcome of postoperative pain management including pain intensity, physical and emotional functional interference, side effects, and perceptions of care. The psychometric quality of the IPO after translation and adaptation to European patients is the focus of this validation study. The aim followed in this paper was not to examine differences between different language versions, but to test how the IPO performs overall in this European population. Reports on the psychometric quality of the instrument for each language separately will be published elsewhere as will focused analysis of perioperative treatment data obtained from the medical record reviews. To our knowledge this is the first study validating a multi-dimensional outcomes questionnaire in a comprehensive, two-step, multi-national validation process in the field of postoperative pain. The IPO was applied to a

total of 9,727 patients in Europe and Israel. It achieved satisfactory psychometric quality both for reliability and for validity.

Numerous validation studies have previously addressed the translation and adaptation of well established instruments like the Brief Pain Inventory (BPI) into one new language[8,34,35,38,23]. The approach taken in this study, to assess reliability and validity of a questionnaire for a combination of languages, has been rarely used[5]. Nevertheless, we achieved satisfactory statistical results. However, it may only be valid when the languages have a high degree of similarity by belonging to the same language family like it is the case here, since most of the languages involved belong to the Indo-European language family. This similarity of languages was also a given in the study cited above[5].

The factor analysis conducted on phase 2 data generated a three factor structure unlike in phase 1, where four factors resulted (see also **Supplemental Information 2** for phase 1 data). The two separate factors 'pain intensity and interference' and 'affective impairment' in phase 1 combined to one composite factor in phase 2, where only 2 affective impairment items ('anxious' and 'helpless') remained. From the perspective of construct validity this combination makes sense. Interference of pain with emotional aspects could be regarded as one facet of interference with "function", in this case emotional functioning. Some instruments for pain measurement follow this notion and ask comprehensively for 'pain interference with mood'[27,19,21,28]. Some authors have reported low factor loadings of 'interference with sleep' for their instruments measuring pain interference[30,36]. However, even after combining the two original items on sleep interference ('falling asleep' and 'staying asleep') into one ('interference with sleep') in the IPO, this item still has a high factor loading of 0.714 in our analysis. The low loading of the item 'interference with breathing/coughing' (0.43) can be explained by left-skewed distribution and its floor effect for orthopedic patients (median 0, m=1.11), whereas in general surgery the values are higher (median 1, m=2.64). Overall reliability of the IPO with a Cronbach's alpha of 0.86 is satisfactory and in line with comparable validation studies[17,2,13,39,22,32]. The high Cronbach's alpha of 0.89 for the subscale 'pain intensity and pain interference (physical and emotional)' confirms the homogeneity of

this subscale, even after inclusion of the two items on emotional impairment. Internal consistency for the subscale 'adverse effects' is with 0.67 very close to the APS result, whereas the 'perceptions of care' subscale achieves a lower, questionable Cronbach's alpha (0.53 vs. 0.70) in our study[17]. The low values for these subscales have substance matter explanations: Their items do not follow the classic notion of measurement of one dimension. This is particularly true for the 'perceptions of care' scale. Nevertheless, all three components of this scale convey very important information and are needed in the questionnaire. Especially for the subscale 'perceptions of care' it may however be worth considering whether the 3 items concerned should be treated separately instead of combining them into a scale. In the case of 'adverse events', a common scale may make more sense but it should be noted that we do not expect these items to be highly correlated as different approaches to pain treatment can lead to different patterns of adverse events.

Substantial differences in pain treatment outcomes in various surgical disciplines are documented[27,41]. The criterion to establish discriminant validity used in this study was therefore the outcome difference between the two disciplines general and orthopedic surgery. Indeed, the significant outcome differences found in our study between general surgery and orthopedic surgery patients confirm discriminant validity of the instrument. Pain intensity and pain interference is increased in orthopedic patients. The increased mean score for 'interference with breathing/coughing' in the general surgery patient group is also plausible given the surgical sites involved. The increased values in the items 'percentage of pain relief from all pain treatments combined (medicine and non-medicine)' and 'satisfaction with pain treatment' in general surgery patients are well in line with the lower pain intensity and functional interference values in this discipline. The increased score for the item 'Participation in decision making' in orthopedic patients cannot be explained easily and may mirror differences in provider practices or patient populations in the two surgical disciplines in question.

In contrast to the APS-POQ-R, our questionnaire asks patients about chronic pain before surgery. This combination may allow gaining new insights into the interaction between

chronic and acute pain with regard to treatment responses. To this end, PAIN OUT is collaborating with the European observational study on Chronic Post Surgical Pain (euCPSP) project, supported by the European Society of Anaesthesiology. Thus, PAIN OUT is providing means to link acute pain data in the registry with data on chronification collected by euCPSP[12].

*Limitations*

A number of limitations apply to this study. First, not all factors potentially influencing patients' pain outcomes could be collected, which may limit the range of additional research questions that can be addressed with the currently collected data. Specifically, we did not collect data about socioeconomic status and level of education, though there is evidence indicating that both are influential in patient's assessment of pain[9,18,7]. PAIN OUT records ethnicity of patients in the demographics section of the questionnaire in countries where this is recorded, yet this task remains a challenge. Interestingly, cultural differences in approaching these issues and deviating attitudes about political correctness throughout Europe, constituting themselves part of ethnical differences, make it difficult to obtain consistent data on patient ethnicity.

The validity of the IPO can only be assumed for the patient population contributing to this study, i.e. adults with normal cognitive functioning. Children, cognitively impaired patients, and other languages are excluded.

It would have been interesting to compare outcomes between the different countries involved in the project. However, apart from one country with three clinical sites for data collection, all other countries contributed with data from only one clinical site. At this stage of the project comparisons between countries have to be treated with caution, since differences found may well be due to site specific effects rather than language or country related differences. So far, we know hardly anything about outcome differences in various countries. At the current stage, outcome differences between countries would be too weak criteria for discriminant validity and would therefore be no useful approach in a validation study. However, in-depth

analysis of country specific outcome differences are currently carried out and a separate publication addressing this topic is in preparation.

In the setting of postoperative pain it might be worthwhile to focus further research on a better adaptation of pain interference items on the surgical discipline in question. E.g. for maxillofacial surgery it could be useful to have patients assessing 'pain interference with eating/chewing'. Further research is underway to examine variations in treatment patterns and how these interact with patient outcomes.

Since this was the first time the IPO was used in a larger patient population further studies need to cross-validate and confirm the dimensionality, reliability, and validity of the IPO.

*Conclusions*

The rationale for developing and testing the IPO was to create a standard, uniform methodology for assessing patient reported outcomes when creating the PAIN OUT registry for a primary non-English European population. The questionnaire will be used in Europe and worldwide. It is piloted already in clinical sites in South-East Asia, Australia, Africa, and the US, which participate in the international branch of the project. The validation process for the non-European countries is currently ongoing. Using this standard methodology will allow for better communication between clinicians and researchers, facilitating QI and large scale epidemiologic studies that have not been possible to conduct before.

**Disclosure**

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None of the authors holds a conflict of interest.

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**Figure legends**

**Figure 1:** Validation process flowchart

**Figure 2:** Case numbers for phase 1 and 2 per clinical site

**Table 1:** Number of patients (%) excluded.

| Exclusion criteria | N=6,795 |
|---|---|
| Not being in the ward for at least 6 hours on post-operative day 1 | 7.1% |
| Patient under consenting age | 1.3% |
| Patient is not available/not on the ward or discharged | 10.1% |
| Patient did not give assent | 7.1% |
| Patient is too ill | 3.6% |
| Patient is asleep | 9.5% |
| Problems in understanding/ language problems | 2.4% |
| Patient is cognitively impaired | 1.2% |
| Other reasons | 2.7% |

**Table 2:** Demographics

| | Demographic data | |
|---|---|---|
| **Characteristics** | N | Value |
| Female gender; frequency (%) | 4,573 | 2,287 (50.0) |
| Age; mean years ± SD; range | 4,552[2] | 54.4±17.1; 15-103 |
| Language version used; frequency (%) | 4,146 | |
| German | | 1,338 (32.3) |
| Italian | | 490 (11.8) |
| Spanish | | 330 (8.0) |
| French | | 489 (11.8) |
| Romanian | | 476 (11.5) |
| Swedish | | 450 (10.9) |
| Hebrew | | 349 (8.4) |
| English | | 197 (4.8) |
| Other[1] | | 27 (0.6) |
| Ward specialty; frequency (%) | 4,590 | |
| General surgery | | 1,934 (42.1) |
| Orthopedics | | 2,538 (55.3) |
| Other, unknown or missing | | 118 (2.6) |

[1] Translations into additional languages (e.g. Russian and Arabic) representing relevant minorities in the some of the participating countries are also available.

**Table 3a:** Frequencies, means, and standard deviations for NRS items.

| NRS Items | N | Mean | SD |
|---|---|---|---|
| Least pain in 24 hours | 4,554 | 1.77 | 1.87 |
| Worst pain in 24 hours | 4,576 | 5.16 | 2.83 |
| Percentage of time in severe pain[2] | 4,468 | 2.64 | 2.60 |
| Pain interference with activities in bed | 4,458 | 4.28 | 3.17 |
| Pain interference with activities out of bed | 3,186[3] | 3.36 | 2.88 |
| Pain interference with breathing/coughing | 4,471 | 1.78 | 2.67 |
| Pain interference with sleep | 4,482 | 2.84 | 3.07 |
| Emotional impairment due to pain: anxious | 4,513 | 2.14 | 2.74 |
| Emotional impairment due to pain: helpless | 4,460 | 2.26 | 3.04 |
| Adverse effects: nausea | 4,528 | 1.70 | 2.78 |
| Adverse effects: drowsiness | 4,508 | 2.70 | 2.98 |
| Adverse effects: itching | 4,486 | 0.54 | 1.62 |
| Adverse effects: dizziness | 4,511 | 1.71 | 2.50 |
| Percentage of pain relief from all treatments combined | 4,255 | 6.92 | 2.70 |
| Participation in decision making | 4,169 | 5.88 | 3.95 |
| Satisfaction with pain treatment | 4,333 | 8.20 | 2.17 |
| Intensity of persistent pain before surgery | 2,313 | 6.25 | 2.36 |

[2] Percentage scales were transferred to a 0 – 10 scale to facilitate comparison

[3] This N is lower because the questionnaire contains a complementary items asking whether patients had been out of bed already. Only if this question was answered with 'yes' the item on pain interference with activities out of bed was scored.

**Table 3b:** Frequencies and percentages for binary and categorical items

| **Binary items (% 'yes' answers)** | **N** | **%** |
|---|---|---|
| Information about pain treatment options | 4,513 | 64.72 |
| Use of non-medicine methods for pain relief | 4,531 | 43.77 |
| Wish for more pain treatment | 4,519 | 16.93 |
| Persistent painful condition before surgery | 4,539 | 52.63 |
| **Categorical items (% per category)** | N | % |
| Location of persistent pain before surgery | 2,330 | 100.00 |
| | site of surgery | 62.19 |
| | elsewhere | 9.10 |
| | both | 28.71 |

**Table 4:** Rotated component matrix of factor loadings for NRS items.

| | Components | | |
|---|---|---|---|
| | 1 | 2 | 3 |
| | Pain intensity and interference | Adverse effects | Perceptions of care |
| Explained variance (**total: 53.58%**) | 36.00% | 10.31% | 7.49% |
| Worst pain in 24 hours | .775. | .262. | -.204. |
| Least pain in 24 hours | .722. | .184. | -.262. |
| Percentage of time in severe pain | .805. | .186. | -.280. |
| Pain interference with activities in bed | .752. | .337. | -.191. |
| Pain interference with breathing or coughing | .495. | .349. | -.125. |
| Pain interference with sleep | .743. | .229. | -.211. |
| Pain interference with activities out of bed | .777. | .321. | -.195. |
| Emotional impairment due to pain: anxious | .686. | .386. | -.171. |
| Emotional impairment due to pain: helpless | .717. | .415. | -.172. |
| Adverse effects: nausea | .271. | .736. | -.022. |
| Adverse effects: drowsiness | .289. | .772. | -.106. |
| Adverse effects: itching | .209. | .448. | -.067. |
| Adverse effects: dizziness | .369. | .767. | -.049. |
| Percentage of pain relief in 24 hours | -.489. | .029. | .608. |
| Participation in decision making | .001. | -.093. | .774. |
| Satisfaction with pain treatment | -.489. | -.080. | .734. |

**Table 5:** Cronbach's alpha and item-to-subscale (item-rest) correlations for the 16 NRS items and for the three subscales.

| Item | N | Sign | Item-test correlation | Item-rest correlation | Average inter-item correlation | alpha |
|---|---|---|---|---|---|---|
| Worst pain in 24 hours | 4576 | + | 0.71 | 0.65 | 0.27* | 0.85* |
| Least pain in 24 hours | 4554 | + | 0.67 | 0.60 | 0.28* | 0.85* |
| Percentage of time in severe pain | 4468 | + | 0.72 | 0.66 | 0.27* | 0.85* |
| Pain interference with activities in bed | 4458 | + | 0.71 | 0.65 | 0.27* | 0.85* |
| Pain interference with breathing or coughing | 4471 | + | 0.53 | 0.44 | 0.29* | 0.86* |
| Pain interference with sleep | 4482 | + | 0.68 | 0.61 | 0.28* | 0.85* |
| Pain interference with activities out of bed | 3186 | + | 0.72 | 0.66 | 0.28* | 0.85* |
| Emotional impairment due to pain: anxious | 4513 | + | 0.68 | 0.61 | 0.28* | 0.85* |
| Emotional impairment due to pain: helpless | 4460 | + | 0.71 | 0.64 | 0.27* | 0.85* |
| Adverse effects: nausea | 4528 | + | 0.46 | 0.36 | 0.30 | 0.86* |
| Adverse effects: drowsiness | 4508 | + | 0.49 | 0.40 | 0.29* | 0.86* |
| Adverse effects: itching | 4486 | + | 0.35 | 0.25 | 0.31* | 0.87* |
| Adverse effects: dizziness | 4511 | + | 0.54 | 0.45 | 0.29 | 0.86* |
| Percentage of pain relief in 24 hours | 4255 | + | 0.49 | 0.40 | 0.29* | 0.86* |
| Participation in decision making | 4169 | + | 0.20 | 0.09 | 0.32* | 0.87* |
| Satisfaction with pain treatment | 4333 | + | 0.54 | 0.45 | 0.29* | 0.86* |
| Test scale | | | | | 0.28 | **0.86** |
| **Subscales** | | | | | | |
| 'Pain intensity and interference (physical and emotional)' | 4576 | - | - | - | 0.47 | **0.89** |
| 'Adverse effects' | 4528 | - | - | - | 0.33 | **0.67** |
| 'Perceptions of care' | 4333 | - | - | - | 0.29 | **0.55** |

* For test scale, if item removed from test scale.

**Table 6:** Significant differences of 16 items for type of surgery (general versus orthopedic surgery).

| Item | N General surgery | Mean General surgery | Standard deviation | N Ortho.[4] surgery | Mean Ortho. surgery | Standard deviation | p value Mann-Whitney U test* |
|---|---|---|---|---|---|---|---|
| Worst pain in 24 hours | 1,922 | 4.61 | 2.91 | 2,536 | 5.60 | 2.69 | <0.001 |
| Least pain in 24 hours | 1,917 | 1.53 | 1.78 | 2,520 | 1.96 | 1.93 | <0.001 |
| Percentage of time in severe pain | 1,883 | 2.12 | 2.46 | 2,467 | 3.07 | 2.65 | <0.001 |
| Pain interference with activities in bed | 1,878 | 3.98 | 3.19 | 2,463 | 4.53 | 3.15 | <0.001 |
| Pain interference with breathing or coughing | 1,881 | 2.64 | 3.08 | 2,474 | 1.11 | 2.09 | <0.001 |
| Pain interference with sleep | 1,882 | 2.32 | 3.00 | 2,486 | 3.24 | 3.08 | <0.001 |
| Pain interference with activities out of bed | 1,628 | 2.87 | 2.86 | 1,451 | 3.97 | 2.84 | <0.001 |
| Emotional impairment due to pain: anxious | 1,899 | 1.97 | 2.77 | 2,497 | 2.28 | 2.72 | <0.001 |
| Emotional impairment due to pain: helpless | 1,864 | 1.95 | 2.94 | 2,479 | 2.51 | 3.11 | <0.001 |
| Adverse effects: nausea | 1,901 | 1.75 | 2.87 | 2,509 | 1.67 | 2.71 | 0.803 |
| Adverse effects: drowsiness | 1,891 | 2.99 | 3.09 | 2,501 | 2.51 | 2.89 | <0.001 |
| Adverse effects: itching | 1,876 | 0.51 | 1.62 | 2,494 | 0.57 | 1.64 | 0.009 |
| Adverse effects: | 1,894 | 1.85 | 2.63 | 2,500 | 1.58 | 2.38 | 0.002 |

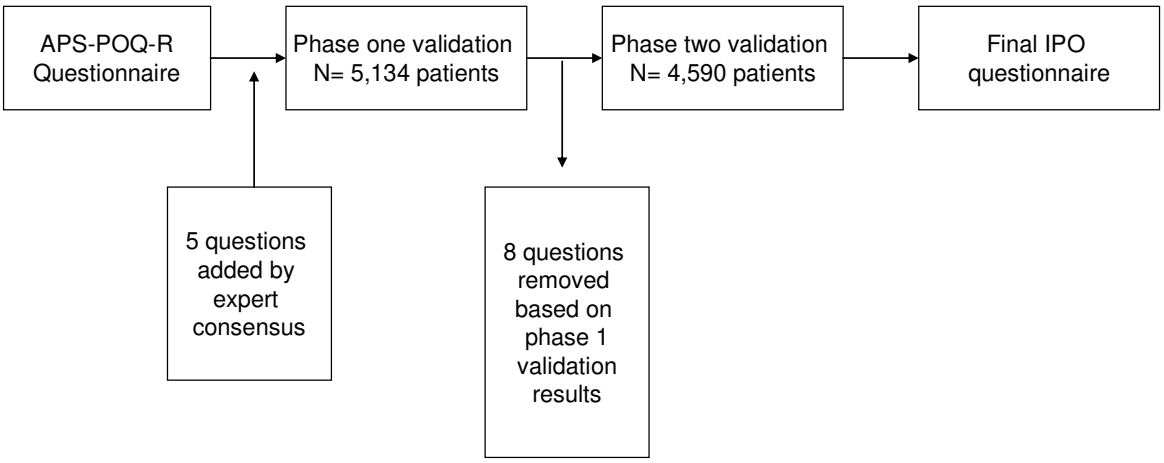
[4] Orthopedic surgery

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| dizziness | | | | | | | |
| Percentage of pain relief in 24 hours | 1,763 | 7.25 | 2.80 | 2,377 | 6.65 | 2.61 | <0.001 |
| Participation in decision making | 1,756 | 5.20 | 4.25 | 2,300 | 6.33 | 3.64 | <0.001 |
| Satisfaction with pain treatment | 1,811 | 8.55 | 2.01 | 2,404 | 7.93 | 2.25 | <0.001 |
| **Binary item** | **N General Surgery** | **% 'yes' General surgery** | | **N Ortho. surgery** | **% 'yes' Ortho. surgery** | | **p value Chi$^2$ test** |
| Information on pain treatment options received | 1,905 | 58.8 | -- | 2,490 | 68.7 | -- | <0.001 |
| Use of non-medicine methods for pain relief | 1,909 | 34.3 | -- | 2,504 | 51.2 | -- | <0.001 |

* Results of T-tests run in parallel for comparison purposes were highly consistent with Mann-Whitney U test results.

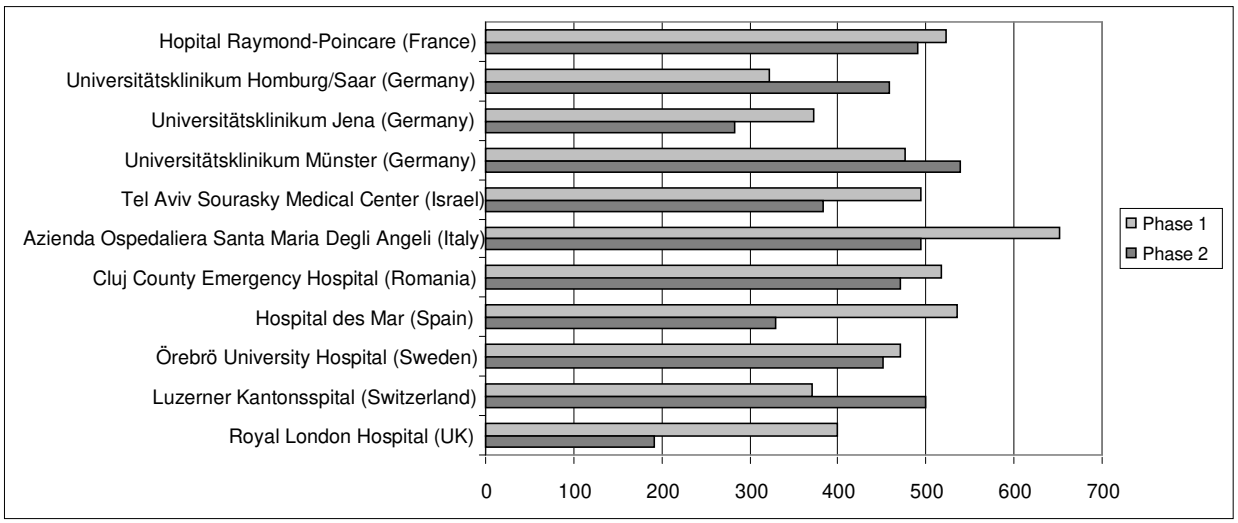
**Figure**

**Figure 1:** Validation process flowchart



**Figure**

**Figure 2:** Case numbers for phase 1 and 2 per clinical site



**Tables**

**Supplemental Information 1:** List of PAIN OUT project partners

**EU funded PAIN OUT partners** (European Commission 7th Framework Programme, Call HEALTH-2007-3.1-4: Improving clinical decision making)

**Clinical sites:**

University Hospital Jena, Germany (project coordinator)

Institut Municipal D'Assistencia Sanitaria, Barcelona, Spain

Charité Universitaetsmedizin Berlin, Germany

Spitalul Clinic Judetean De Urgenta, Cluj Napoca, Romania

Universität des Saarlandes, Homburg/Saar, Germany

Queen Mary And Westfield College, University of London, UK

Luzerner Kantonsspital, Switzerland

Westfälische Wilhelms University Münster, Germany

Universitetssjukhuset Örebro, Sweden

Assistance Publique – Hopitaux de Paris, France

Azienda Ospedaliera Santa Maria Degli Angeli, Pordenone, Italy

The Tel-Aviv Sourasky Medical Center, Israel

**Research partners:**

European Center of Pharmaceutical Medicine (ECPM), University Basel, Switzerland

Peninsula Medical School, University of Exeter, UK

University Leipzig, Institute for Medical Informatics, Statistics and Epidemiology (IMISE), Germany

Mälardalen University, Sweden

TAKWA GmbH, Erfurt, Germany

**PAIN OUT International partners**

Universitair Ziekenhuis Antwerpen, Belgium

Cliniques Universitaires Saint Luc, Brussels, Belgium

Clinica Iquique S.A., Chile

Kuopio University Hospital, Finland

GHN Hôpital de la Croix Rouge, Lyon, France

GHC Cochin, Paris, France

Klinikum Darmstadt GmbH, Germany

Universitätsklinikum Würzburg, Germany

Cork University Hospital, Ireland

Azienda Ospedaliero Universitaria, Policlinico Vittorio Emanuele Catania, Italy

University of Foggia, Policlinico Riuniti, Italy

Azienda Ospedaliera Niguarda, Milano, Italy

Seconda Università di Napoli, Napoli, Italy

University of Rome, Policlinico Umberto I, Italy

University Malaya Medical Centre, Kuala Lumpur, Malaysia

National Scientific Centre of Emergency Medicine, Chişinău, Republic of Moldova

Emergency Institute of Cardiovascular. Diseases, Bucharest, Romania

Central Military Hospital Dr. Carol Davina, Bucharest, Romania

Spitalul Clinic  Judetean de Urgenta Constanta, Romania

Arcadia Hospital, Iasi, Romania

Spital Clinic Cuza-Voda, Iasi, Romania

Kigali University Hospital, Rwanda

Clinical Center of Vojvodina, Serbia

Chosun University Hospital, South Korea

Konyang University Hospital, Daejeon, Korea

Hospital San Juan de Alicante, Spain

Hospital Clinic de Barcelon, Spain

Parc Sanitari Sant Joan de Deu, Barcelona, Spain

Hospital de Galdankao-Usansola, Galdakao Bizkaia, Spain

Capio Clinica Virgen de Guadalupe, Cacerés, Spain

Hospital General de Castellón, Spain

Hospital General de Ciudad Real, Spain

Hospital Universitario Virgen de las Nieves, Granada, Spain

Hospital La Inmaculada, Huércal-Overa, Spain

Complejo Hospital Universitario, Las Palmas de Gran Canaria, Spain

Hospital Universitario 12 de Octubre, Madrid, Spain

Hospital Regional Universitario Carlos Haya, Malaga, Spain

Hospital Son Llatzer, Palma de Mallorca, Spain

Hospital Dr. Peset, Valencia, Spain

University Hospital La Fe, Valencia, Spain

University Clinical Hospital Valladolid, Spain

St. Claraspital, Basel, Switzerland

University Hospital Basel, Switzerland

Inselspital Bern, Switzerland

Hôpitaux Universitaires de Genève, Switzerland

Centre Hospitalier Universitaire Vaudois, Lausanne, Switzerland

Ensemble hospitalier de la côte (EHC), Morges, Switzerland

City Hospital Triemli, Zurich, Switzerland

University College Hospital London, UK

Nottingham University Hospitals NHS Trust, UK

Torbay Hospital, Torquay Devon, UK

Kyiv City Clinical Hospital # 17, Kyiv, Ukraine

National Cancer Institute Kiev, Ukraine

Hospital of Crimea State Medical University, Simferopol, Ukraine

Zhitomir Regional Oncological Center, Ukraine

NorthShore University HealthSystem, Evanston, IL, USA

UWHealth University of Wisconsin Hospital and Clinics, Madison, USA

Hospital of the University of Pennsylvania, Philadelphia, USA

Oregon Health and Science University, Portland, US

## Supplemental Information 2

### Phase 1 validation results

#### *Exploratory factor analysis*

An exploratory factor analysis was carried out including all 18 NRS items using principal component analysis with promax rotation to assess construct validity. Pairwise exclusion of missing values was applied and resulted in case numbers ranging from 4,238 to 5,108. The results are comprised in **table 1**. The four resulting factors with an Eigen value >1 achieved a total explained variance of 60.78%. All items except one reached very satisfying factor loadings >.63. The factor structure is comparable to the results for the APS-POQ-R[11] and we therefore chose to retain the same naming of these factors as described in this previous publication. The first factor, 'pain intensity and interference', consists of the three items on pain intensity (least pain, worst pain, and time spent in severe pain) and the four items addressing pain interference (with activities in bed, with activities out of bed, with falling asleep, and with staying asleep). The second factor comprises the four items on emotional impairment due to pain ('anxious', 'depressed', 'frightened', and 'helpless') and was named 'affective impairment'. The four items dealing with side effects ('nausea', 'drowsiness', 'itching', and 'dizziness') load on the third factor 'adverse effects'. The fourth factor, 'perceptions of care', includes three relatively heterogeneous items 'pain relief', 'participation in decisions on pain treatment', and 'satisfaction with pain treatment'.

#### *Internal consistency reliability*

Cronbach's alpha and related statistics were calculated at item level (see **Table 2**) for the 18 NRS items and for the subscales identified in factor analysis (see **Table 3**). Overall Cronbach's alpha was 0.88. At the subscale level internal consistency was best for 'pain intensity and interference' (r=.89), followed by 'affective impairment' (r=.87) and 'adverse effects' (r=.67). The 'perceptions of care' subscale showed the lowest internal consistency (r=.53).

#### *Discriminant validity*

**Table 4** summarizes to what extent the 18 NRS items differentiated between patients treated in general surgery versus in orthopaedic wards based on Mann-Whitney-U tests. All pain severity and interference items were significantly increased in patients treated in orthopaedic wards. Items ‘percentage of pain relief’ and ‘satisfaction with pain treatment’ were significantly decreased, indicating the same direction of association. Average scores were also higher in all affective items, although these differences for the items ‘feeling anxious’ and ‘feeling frightened’ were not significant. The adverse effect ‘nausea’ was significantly higher in the general surgery patient group. The item ‘participation in decision making’ showed significantly higher scores in patients treated in orthopaedic wards, who also received more information of pain treatment and used more frequently non-medicine methods of pain relief.

**Table 1:** Rotated component matrix of factor loadings for NRS items for phase 1 data.

| | Components | | | |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4 |
| | Pain intensity and interference | Affective impairment | Adverse effects | Perceptions of care |
| Explained variance (**total: 60.78%**) | 36.21% | 9.87% | 7.62% | 7.07% |
| Least pain in 24 hours | ,716 | ,416 | ,239 | -,198 |
| Worst pain in 24 hours | ,800 | ,369 | ,352 | -,216 |
| Percentage of time in severe pain | ,786 | ,411 | ,237 | -,288 |
| Pain interference with activities in bed | ,775 | ,408 | ,430 | -,136 |
| Pain interference with activities out of bed | ,745 | ,421 | ,442 | -,111 |
| Pain interference with falling asleep | ,804 | ,481 | ,208 | -,158 |
| Pain interference with staying asleep | ,791 | ,484 | ,223 | -,147 |
| Emotional impairment due to pain: anxious | ,493 | ,848 | ,311 | -,143 |
| Emotional impairment due to pain: depressed | ,529 | ,777 | ,404 | -,102 |
| Emotional impairment due to pain: frightened | ,472 | ,865 | ,312 | -,122 |
| Emotional impairment due to pain: helpless | ,419 | ,881 | ,345 | -,092 |
| Adverse effects: nausea | ,270 | ,241 | ,761 | -,036 |
| Adverse effects: drowsiness | ,334 | ,309 | ,777 | -,001 |
| Adverse effects: itching | ,219 | ,289 | ,438 | -,087 |
| Adverse effects: dizziness | ,305 | ,350 | ,781 | -,020 |
| Percentage of pain relief in 24 hours | -,429 | -,181 | -,019 | ,626 |
| Participation in decision making | ,075 | ,033 | -,017 | ,716 |
| Satisfaction with pain treatment | -,363 | -,235 | -,066 | ,778 |

**Table 2:** Cronbach's alpha and item-to-subscale (item-rest) correlations for the 18 NRS item for phase 1 data

| Item | N | Sign | Item-test correlation | Item-rest correlation | Average inter-item correlation | Cronbach's Alpha |
|---|---|---|---|---|---|---|
| Least pain in 24 hours | 5104 | + | 0.65 | 0.58 | 0.29 | 0.87 |
| Worst pain in 24 hours | 5108 | + | 0.70 | 0.65 | 0.28 | 0.87 |
| Percentage of time in severe pain | 4948 | + | 0.69 | 0.64 | 0.28 | 0.87 |
| Pain interference with activities in bed | 5007 | + | 0.71 | 0.65 | 0.28 | 0.87 |
| Pain interference with activities out of bed | 4240 | + | 0.69 | 0.63 | 0.28 | 0.87 |
| Pain interference with falling asleep | 5033 | + | 0.70 | 0.65 | 0.28 | 0.87 |
| Pain interference with staying asleep | 5002 | + | 0.70 | 0.64 | 0.28 | 0.87 |
| Emotional impairment due to pain: anxious | 5049 | + | 0.67 | 0.61 | 0.28 | 0.87 |
| Emotional impairment due to pain: depressed | 5027 | + | 0.66 | 0.60 | 0.28 | 0.87 |
| Emotional impairment due to pain: frightened | 5029 | + | 0.64 | 0.58 | 0.29 | 0.87 |
| Emotional impairment due to pain: helpless | 5003 | + | 0.68 | 0.62 | 0.28 | 0.87 |
| Adverse effects: nausea | 5,097 | + | 0.45 | 0.37 | 0.30 | 0.88 |
| Adverse effects: drowsiness | 5077 | + | 0.51 | 0.43 | 0.30 | 0.88 |
| Adverse effects: itching | 5086 | + | 0.38 | 0.29 | 0.31 | 0.88 |
| Adverse effects: dizziness | 5,078 | + | 0.51 | 0.43 | 0.30 | 0.88 |
| Percentage of pain relief in 24 hours | 4727 | - | 0.43 | 0.34 | 0.30 | 0.88 |
| Participation in decision making | 4772 | - | 0.11 | 0.01 | 0.33 | 0.89 |
| Satisfaction with pain treatment | 4859 | - | 0.44 | 0.36 | 0.30 | 0.88 |
| Test scale | | | | | 0.29 | **0.88** |

**Table 3:** Cronbach's alpha and item-to-subscale (item-rest) correlations for the four subscales for phase 1 data

| Subscale and item | N | Sign | Item-test correlation | Item-rest correlation | Average interitem correlation | alpha |
|---|---|---|---|---|---|---|
| **Subscale 'pain intensity and interference'** | | | | | | |
| Least pain in 24 hours | 5104 | + | 0.73 | 0.62 | 0.56 | 0.88 |
| Worst pain in 24 hours | 5108 | + | 0.80 | 0.71 | 0.53 | 0.87 |
| Percentage of time in severe pain | 4948 | + | 0.79 | 0.79 | 0.54 | 0.87 |
| Pain interference with activities in bed | 5007 | + | 0.78 | 0.69 | 0.54 | 0.87 |
| Pain interference with activities out of bed | 4240 | + | 0.76 | 0.66 | 0.55 | 0.88 |
| Pain interference with falling asleep | 5033 | + | 0.81 | 0.72 | 0.53 | 0.87 |
| Pain interference with staying asleep | 5002 | + | 0.79 | 0.70 | 0.54 | 0.87 |
| Test scale | | | | | 0.54 | **0.89** |
| **Subscale 'affective impairment'** | | | | | | |
| Emotional impairment due to pain: anxious | 5049 | + | 0.85 | 0.72 | 0.62 | 0.83 |
| Emotional impairment due to pain: depressed | 5027 | + | 0.86 | 0.74 | 0.61 | 0.82 |
| Emotional impairment due to pain: frightened | 5029 | + | 0.87 | 0.76 | 0.60 | 0.82 |
| Emotional impairment due to pain: helpless | 5003 | + | 0.81 | 0.66 | .066 | 0.86 |
| Test scale | | | | | 0.62 | **0.87** |
| **Subscale 'adverse effects'** | | | | | | |
| Adverse effects: nausea | 5,097 | + | 0.73 | 0.49 | 0.31 | 0.58 |
| Adverse effects: drowsiness | 5077 | + | 0.74 | 0.50 | 0.30 | 0.57 |
| Adverse effects: itching | 5086 | + | 0.59 | 0.28 | 0.45 | 0.71 |
| Adverse effects: dizziness | 5,078 | + | 0.77 | 0.55 | 0.28 | 0.53 |
| Test scale | | | | | 0.34 | **0.67** |

| **Subscale 'perceptions of care'** | | | | | | |
|---|---|---|---|---|---|---|
| Percentage of pain relief in 24 hours | 4727 | + | 0.72 | 0.33 | 0.27 | 0.43 |
| Participation in decision making | 4772 | + | 0.66 | 0.23 | 0.41 | 0.58 |
| Satisfaction with pain treatment | 4859 | + | 0.79 | 0.43 | 0.12 | 0.22 |
| Test scale | | | | | 0.27 | **0.52** |

**Table 4:** Significant mean differences of 18 items for type of surgery (general surgery versus orthopaedics surgery) for phase 1 data

| NRS item | N General surgery | Mean General surgery | N Orthopaedics surgery | Mean Orthopaedics surgery | p value Mann-Whitney U test |
|---|---|---|---|---|---|
| Least pain in 24 hours | 2,324 | 2.22/ | 2,456 | 2.59 | <0.001 |
| Worst pain in 24 hours | 2,322 | 5.01 | 2,464 | 6.07 | <0.001 |
| Percentage of time in severe pain | 2,255 | 2.22 | 2,374 | 3.31 | <0.001 |
| Pain interference with activities in bed | 2,287 | 4.24 | 2,401 | 4.89 | <0.001 |
| Pain interference with activities out of bed | 2,094 | 3.61 | 1,876 | 4.89 | <0.001 |
| Pain interference with falling asleep | 2,296 | 2.51 | 2,418 | 3.60 | <0.001 |
| Pain interference with staying asleep | 2,283 | 2.60 | 2,402 | 3.72 | <0.001 |
| Emotional impairment due to pain: anxious | 2,301 | 2.38 | 2,428 | 2.52 | 0.112 |
| Emotional impairment due to pain: depressed | 2,292 | 1.68 | 2,416 | 1.98 | 0.001 |
| Emotional impairment due to pain: frightened | 2,294 | 1.73 | 2,416 | 1.74 | 0.457 |
| Emotional impairment due to pain: helpless | 2,283 | 1.85 | 2,402 | 2.50 | <0.001 |
| Adverse effects: nausea | 2,326 | 1.95 | 2,450 | 1.93 | 0.497 |
| Adverse effects: drowsiness | 2,314 | 3.12 | 2,444 | 3.06 | 0.408 |
| Adverse effects: itching | 2,316 | 0.55 | 2,449 | 0.69 | 0.007 |
| Adverse effects: dizziness | 2,322 | 1.95 | 2,437 | 1.69 | <0.001 |
| Percentage of pain relief in 24 hours | 2,135 | 6.87 | 2,285 | 6.45 | <0.001 |
| Participation in decision making | 2,167 | 5.31 | 2297 | 5.90 | <0.001 |

| | | | | | |
|---|---|---|---|---|---|
| Satisfaction with pain treatment | 2,204 | 8.58 | 2,338 | 8.01 | <0.001 |
| **Binary item** | **N General Surgery** | **% 'yes' General surgery** | **N Orthopaedics surgery** | **% 'yes' Orthopaedics surgery** | **p value Chi$^2$ test** |
| Information on pain treatment options received | 2,290 | 57.16 | 2,432 | 63.86 | <0.001 |
| Use of non-medicine methods for pain relief | 2,300 | 31.65 | 2,452 | 44.45 | <0.001 |

**Tables**

**Supplemental Information 3:** Item list of the International Pain Outcomes questionnaire (IPO)

| **Item** | **Answer format** |
|---|---|
| P1. On this scale, please indicate the **worst pain** you had since your surgery: | NRS 0-10 |
| P2. On this scale, please indicate the **least pain** you had since your surgery: | NRS 0-10 |
| P3. How often were you in **severe pain** since your surgery?<br>Please circle your best estimate of the percentage of time you experienced **severe pain**: | NRS 0-100% |
| P4. Circle the one number below that best describes how much, since your surgery, **pain interfered with or prevented you from** ... | |
| a. doing **activities in bed** such as turning, sitting up, changing position | NRS 0-10 |
| b. **breathing deeply** or **coughing** | NRS 0-10 |
| c. **sleeping** | NRS 0-10 |
| d. Have you been **out of bed** since your surgery? | yes/no |
| If yes, how much did **pain interfere or prevent you from doing activities out of bed** such as walking, sitting in a chair, standing at the sink: | NRS 0-10 |
| P5. Pain can affect our mood and emotions.<br>On this scale, please circle the one number that best shows how much, since your surgery,<br>**pain caused you to feel** ... | |
| a. **anxious** | NRS 0-10 |
| b. **helpless** | NRS 0-10 |
| P6. Have you had any of the following **side effects** since your surgery?<br>Please circle "0" if no; if yes, circle the one number that best shows the severity of each: | |
| a. **Nausea** | NRS 0-10 |
| b. **Drowsiness** | NRS 0-10 |
| c. **Itching** | NRS 0-10 |
| d. **Dizziness** | NRS 0-10 |

| | |
|---|---|
| P7. Since your surgery, how much **pain relief** have you received?<br>Please circle the one percentage that best shows how much relief you have received from all of your **pain treatments** combined (medicine and non-medicine treatments): | NRS 0-100% |
| P8. Would you have liked **MORE pain treatment** than you received? | yes/no |
| P9. Did you receive any **information** about your **pain treatment** options? | yes/no |
| P10. Were you **allowed to participate in decisions** about your **pain treatment** as much as you wanted to? | NRS 0-10 |
| P11. Circle the one number that best shows how **satisfied** you are with the results of your **pain treatment** since your surgery: | NRS 0-10 |
| P12. Did you use or receive any **non-medicine methods** to relieve your **pain**? | yes/no |
| If yes, **check all** that apply:<br>cold pack, meditation, deep breathing, heat, acupuncture, prayer, talking to medical staff, walking, massage, talking to friends or relatives, relaxation, imagery or visualization, TENS (Transcutaneous Electrical Nerve Stimulation), distraction (like watching TV, listening to music, reading), other (please describe) | |
| P13. Did you have a **persistent painful condition for 3 months** or more before coming into hospital for this surgery? | yes/no |
| a. If yes, **how severe** was the **pain** most of the time?<br>Please circle the number that indicates this. | NRS 0-10 |
| b. If yes, **where** was this **persistent pain** located?<br>Site of surgery, elsewhere, both (site of surgery and elsewhere) | |